

Calendar No. 412

108TH CONGRESS
1ST SESSION

S. 1881

To amend the Federal Food, Drug, and Cosmetic Act to make technical corrections relating to the amendments made by the Medical Device User Fee and Modernization Act of 2002, and for other purposes.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 18, 2003

Mr. ALEXANDER (for himself, Mrs. MURRAY, Mr. GREGG, and Mr. ENZI) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

NOVEMBER 24, 2003

Reported by Mr. GREGG, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to make technical corrections relating to the amendments made by the Medical Device User Fee and Modernization Act of 2002, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Medical Devices Tech-
3 nical Corrections Act”.

4 **SEC. 2. TECHNICAL CORRECTIONS REGARDING PUBLIC**
5 **LAW 107-250.**

6 (a) TITLE I; FEES RELATING TO MEDICAL DE-
7 VICES.—Part 3 of subchapter C of chapter VII of the Fed-
8 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379i et
9 seq.), as added by section 102 of Public Law 107-250
10 (116 Stat. 1589), is amended—

11 (1) in section 737—

12 (A) in paragraph (4)(B), by striking “and
13 for which clinical data are generally necessary
14 to provide a reasonable assurance of safety and
15 effectiveness” and inserting “and for which sub-
16 stantial clinical data are necessary to provide a
17 reasonable assurance of safety and effective-
18 ness”;

19 (B) in paragraph (4)(D), by striking
20 “manufacturing.”;

21 (C) in paragraph (5)(J), by striking “a
22 premarket application” and all that follows and
23 inserting “a premarket application or pre-
24 market report under section 515 or a pre-
25 market application under section 351 of the
26 Public Health Service Act.”; and

1 ~~(D)~~ in paragraph (8), by striking “The
 2 term ‘affiliate’ means a business entity that has
 3 a relationship with a second business entity”
 4 and inserting “The term ‘affiliate’ means a
 5 business entity that has a relationship with a
 6 second business entity (whether domestic or
 7 international)”; and
 8 ~~(2)~~ in section 738—

9 ~~(A)~~ in subsection (a)(1)—

10 (i) in subparagraph (A)—

11 (I) in the matter preceding clause

12 (i) by striking “subsection (d),” and
 13 inserting “subsections (d) and (e),”;

14 (II) in clause (iv), by striking
 15 “clause (i),” and all that follows and
 16 inserting “clause (i).”; and

17 (III) in clause (vii), by striking
 18 “clause (i),” and all that follows and
 19 inserting “clause (i), subject to any
 20 adjustment under subsection
 21 (c)(2)(C)(ii).”; and

22 (ii) in subparagraph (D), in each of
 23 clauses (i) and (ii), by striking “applica-
 24 tion” and inserting “application, report,”;

(B) in subsection (d)(2)(B), beginning in the second sentence, by striking “firms, which show” and inserting “firms, which show”;

(C) in subsection (c)—

(i) in paragraph (1), by striking “Where” and inserting “For fiscal year 2004 and each subsequent fiscal year, where”; and

(ii) in paragraph (2)—

(I) in subparagraph (B), beginning in the second sentence, by striking “firms, which show” and inserting “firms, which show”; and

(II) in subparagraph (C)(i), by striking “Where” and inserting “For fiscal year 2004 and each subsequent fiscal year, where”;

(D) in subsection (f), by striking “for filing”; and

(E) in subsection (h)(2)—

(i) by striking subparagraph (A)(ii) and inserting the following:

“(ii) shall only be collected and available to defray increases in the costs of the resources allocated for the process for the

1 review of device applications (including in-
 2 creases in such costs for an additional
 3 number of full-time equivalent positions in
 4 the Department of Health and Human
 5 Services to be engaged in such process)
 6 over such costs for fiscal year 2002 when
 7 multiplied by the adjustment factor (the
 8 determination of the costs of the resources
 9 allocated for the process for the review of
 10 device applications for fiscal year 2003
 11 through 2007, for purposes of this sub-
 12 paragraph, shall not include costs paid
 13 from fees collected under this section).”;
 14 and

15 (ii) in subparagraph (B)—

16 (I) in clause (ii), by redesignating
 17 subclauses (I) and (II) as items (aa)
 18 and (bb), respectively;

19 (II) by redesignating clauses (i)
 20 and (ii) as subclauses (I) and (II), re-
 21 spectively;

22 (III) by striking “The Secretary”
 23 and inserting the following:

24 “(i) IN GENERAL.—The Secretary”;

25 and

1 (IV) by adding at the end the fol-
 2 lowing:

3 “(ii) MORE THAN 5 PERCENT.—To
 4 the extent such costs are more than 5 per-
 5 cent below the specified level in subpara-
 6 graph (A)(ii), fees may not be collected
 7 under this section for that fiscal year.”

8 (b) TITLE II; AMENDMENTS REGARDING REGULA-
 9 TION OF MEDICAL DEVICES.—

10 (1) INSPECTIONS BY ACCREDITED PERSONS.—

11 Section 704(g) of the Federal Food, Drug, and Cos-
 12 metic Act (21 U.S.C. 374(g)), as added by section
 13 201 of Public Law 107–250 (116 Stat. 1602), is
 14 amended—

15 (A) in paragraph (1), in the first sentence,
 16 by striking “conducting inspections” and all
 17 that follows and inserting “conducting inspec-
 18 tions of establishments that manufacture, pre-
 19 pare, propagate, compound, or process class II
 20 or class III devices, which inspections are re-
 21 quired under section 510(h) or are inspections
 22 of such establishments required to register
 23 under section 510(i).”;

24 (B) in paragraph (6)(A)—

(i) in clause (i), by striking “of the establishment pursuant to subsection (h) or (i) of section 510” and inserting “described in paragraph (1)”;

(ii) in clause (ii)—

(I) in the matter preceding subclause (I)—

(aa) by striking “each inspection” and inserting “inspections”; and

(bb) by inserting “during a 2-year period” after “person”; and

(II) in subclause (I), by striking “such a person” and inserting “an accredited person”;

(iii) in clause (iii)—

(I) in the matter preceding subclause (I), by striking “and the following additional conditions are met:” and inserting “and 1 or both of the following additional conditions are met:”;

(II) in subclause (I), by striking “under subclause (II) of this clause”

1 and inserting “under clause (ii)(H)”;
 2 and

3 ~~(III)~~ in subclause (H), by insert-
 4 ing “or by a person accredited under
 5 paragraph (2)” after “by the Sec-
 6 retary”;

7 (iv) in clause (iv)(I)—

8 (I) in the first sentence—

9 (aa) by striking “the two
 10 immediately preceding inspec-
 11 tions of the establishment” and
 12 inserting “inspections of the es-
 13 tablishment during the previous
 14 4 years”; and

15 (bb) by inserting “section”
 16 after “pursuant to”; and

17 (II) in the third sentence—

18 (aa) by striking “the peti-
 19 tion states a commercial reason
 20 for the waiver”; and

21 (bb) by inserting “not” after
 22 “the Secretary has not deter-
 23 mined that the public health
 24 would”; and

25 (v) in clause (iv)(H)—

1 (I) by inserting “of a device es-
 2 tablishment required to register” after
 3 “to be conducted”; and

4 (II) by inserting “section” after
 5 “pursuant to”;

6 (C) in paragraph (6)(B)(iii)—

7 (i) in the first sentence, by striking “,
 8 and data otherwise describing whether the
 9 establishment has consistently been in
 10 compliance with sections 501 and 502”;
 11 and

12 (ii) in the second sentence—

13 (I) by striking “inspections” and
 14 inserting “inspectional findings”; and

15 (II) by striking “, together with
 16 all other compliance data the Sec-
 17 retary deems necessary”;

18 (D) in paragraph (6)(C)(ii), by striking “in
 19 accordance with section 510(h), or has not dur-
 20 ing such period been inspected pursuant to sec-
 21 tion 510(i), as applicable”;

22 (E) in paragraph (10)(B)(iii), by striking
 23 “a reporting” and inserting “a report”; and

24 (F) in paragraph (12)—

1 (i) by striking subparagraph (A) and
 2 inserting the following:

3 “(A) the number of inspections conducted
 4 by accredited persons pursuant to this sub-
 5 section and the number of inspections con-
 6 ducted by Federal employees pursuant to sec-
 7 tion 510(h) and of device establishments re-
 8 quired to register under section 510(i);” and

9 (ii) in subparagraph (E), by striking
 10 “obtained by the Secretary” and all that
 11 follows and inserting “obtained by the Sec-
 12 retary pursuant to inspections conducted
 13 by Federal employees;”.

14 (2) OTHER CORRECTIONS.—Section 502(f) of
 15 the Federal Food, Drug, and Cosmetic Act (21
 16 U.S.C. 352(f)), as amended by section 206 of Public
 17 Law 107–250 (116 Stat. 1613), is amended, in the
 18 last sentence—

19 (A) by inserting “or by a health care pro-
 20 fessional and required labeling for in vitro diag-
 21 nostic devices intended for use by health care
 22 professionals or in blood establishments” after
 23 “in health care facilities”;

24 (B) by inserting a comma after “means”;

(C) by striking “requirements of law and, that” and inserting “requirements of law, and that”;

(D) by striking “the manufacturer affords health care facilities the opportunity” and inserting “the manufacturer affords such users the opportunity”; and

(E) by striking “the health care facility”.

(c) ~~TITLE III; ADDITIONAL AMENDMENTS.~~—Section 510(o) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(o)), as added by section 302(b) of Public Law 107–250 (116 Stat. 1616), is amended—

(1) in paragraph (1)(B), by striking “, adulterated” and inserting “or adulterated”; and

(2) in paragraph (2)—

(A) in subparagraph (B), by striking “, adulterated” and inserting “or adulterated”; and

(B) in subparagraph (E), by striking “semicritical” and inserting “semi-critical”.

(d) ~~MISCELLANEOUS CORRECTIONS.~~—

(1) ~~CERTAIN AMENDMENTS TO SECTION 515.~~—

(A) ~~IN GENERAL.~~—

(i) ~~TECHNICAL CORRECTION.~~—Section 515(c) of the Federal Food, Drug, and

1 Cosmetic Act (~~21 U.S.C. 360e(c)~~), as
 2 amended by sections 209 and 302(e)(2)(A)
 3 of Public Law 107–250 (116 Stat. 1613,
 4 1618), is amended by redesignating para-
 5 graph (3) (as added by section 209 of such
 6 Public Law) as paragraph (4).

7 (ii) MODULAR REVIEW.—Section
 8 515(e)(4)(B) of the Federal Food, Drug,
 9 and Cosmetic Act (~~21 U.S.C.~~
 10 ~~360e(c)(4)(B)~~) is amended by striking
 11 “unless an issue of safety” and inserting
 12 “unless a significant issue of safety”.

13 (B) CONFORMING AMENDMENT.—Section
 14 210 of Public Law 107–250 (116 Stat. 1614)
 15 is amended by striking “, as amended” and all
 16 that follows through “by adding” and inserting
 17 “is amended in paragraph (3), as redesignated
 18 by section 302(e)(2)(A) of this Act, by adding”.

19 (2) CERTAIN AMENDMENTS TO SECTION 738.—

20 (A) IN GENERAL.—Section 738(a) of the
 21 Federal Food, Drug, and Cosmetic Act (~~21~~
 22 ~~U.S.C. 379j(a)~~), as amended by subsection (a),
 23 is amended—

24 (i) in the matter preceding paragraph
 25 (1)—

1 (I) by striking “(a) TYPES OF
2 FEES.—Beginning on” and inserting
3 the following:

4 “(a) TYPES OF FEES.—

5 “(1) IN GENERAL.—Beginning on”; and

6 (II) by striking “this section as
7 follows:” and inserting “this section.”;
8 and

9 (ii) by striking “(1) PREMARKET AP-
10 PLICATION,” and inserting the following:

11 “(2) PREMARKET APPLICATION.”

12 (B) CONFORMING AMENDMENTS.—Section
13 738 of the Federal Food, Drug, and Cosmetic
14 Act (21 U.S.C. 379j), as amended by subpara-
15 graph (A), is amended—

16 (i) in subsection (d)(1), in the last
17 sentence, by striking “subsection
18 (a)(1)(A)” and inserting “subsection
19 (a)(2)(A)”;

20 (ii) in subsection (e)(1), by striking
21 “subsection (a)(1)(A)(vii)” and inserting
22 “subsection (a)(2)(A)(vii)”;

23 (iii) in subsection (e)(2)(C)—

24 (I) in each of clauses (i) and (ii),
25 by striking “subsection (a)(1)(A)(vii)”

1 and inserting “subsection
 2 (a)(2)(A)(vii)”; and
 3 (H) in clause (ii), by striking
 4 “subsection (a)(1)(A)(i)” and insert-
 5 ing “subsection (a)(2)(A)(i)”; and
 6 (iv) in subsection (j), by striking
 7 “subsection (a)(1)(D),” and inserting
 8 “subsection (a)(2)(D),”.

9 (C) ~~ADDITIONAL CONFORMING AMEND-~~
 10 ~~MENT.~~—Section 102(b)(1) of Public Law 107-
 11 250 (116 Stat. 1600) is amended, in the matter
 12 preceding subparagraph (A), by striking “sec-
 13 tion 738(a)(1)(A)(ii)” and inserting “section
 14 738(a)(2)(A)(ii)”.

15 (3) ~~PUBLIC LAW 107-250.~~—Public Law 107-
 16 250 is amended—

17 (A) in section 102(a) (116 Stat. 1589), by
 18 striking “(21 U.S.C. 379F et seq.)” and insert-
 19 ing “(21 U.S.C. 379f et seq.)”;

20 (B) in section 102(b) (116 Stat. 1600)—

21 (i) by striking paragraph (2);

22 (ii) in paragraph (1), by redesignating
 23 subparagraphs (A) and (B) as paragraphs
 24 (1) and (2), respectively; and

25 (iii) by striking:

1 ~~“(b) FEE EXEMPTION FOR CERTAIN ENTITIES SUB-~~
 2 ~~MITTING PREMARKET REPORTS.—~~

3 ~~“(1) IN GENERAL.—A person submitting a pre-~~
 4 ~~market report” and inserting:~~

5 ~~“(b) FEE EXEMPTION FOR CERTAIN ENTITIES SUB-~~
 6 ~~MITTING PREMARKET REPORTS.—A person submitting a~~
 7 ~~premarket report”;~~

8 ~~(C) in section 212(b)(2) (116 Stat. 1614),~~
 9 ~~by striking “, such as phase IV trials,”; and~~

10 ~~(D) in section 301(b) (116 Stat. 1616), by~~
 11 ~~striking “18 months” and inserting “36~~
 12 ~~months”.~~

13 **SEC. 3. HUMANITARIAN DEVICE EXEMPTION AND PEDI-**
 14 **ATRIC PRODUCTS.**

15 ~~(a) AMENDMENT TO FEDERAL FOOD, DRUG, AND~~
 16 ~~COSMETIC ACT.—Section 520(m)(3) of the Federal Food,~~
 17 ~~Drug, and Cosmetic Act (21 U.S.C. 360j(m)(3)) is amend-~~
 18 ~~ed to read as follows:~~

19 ~~“(3) Excluding devices intended for the treatment or~~
 20 ~~diagnosis of diseases or conditions that affect pediatric pa-~~
 21 ~~tients, no person granted an exemption under paragraph~~
 22 ~~(2) with respect to a device may sell the device for an~~
 23 ~~amount that exceeds the costs of research and develop-~~
 24 ~~ment, fabrication, and distribution of the device. The ex-~~
 25 ~~clusion from the prohibition under the previous sentence~~

1 for devices intended for the treatment or diagnosis of dis-
 2 eases or conditions that affect pediatric patients; shall not
 3 apply in the case of a request for an exemption under
 4 paragraph (2) made on or after October 1, 2007. In this
 5 paragraph, the term ‘pediatric patient’ means a patient
 6 who is 14 years of age or younger at the time of diagnosis
 7 or treatment.’’.

8 (b) REPORT.—Not later than October 1, 2006, the
 9 Comptroller General of the United States, in consultation
 10 with the Secretary of Health and Human Services, shall
 11 submit to Congress a report that addresses the effective-
 12 ness of section 520(m) of the Federal Food, Drug, and
 13 Cosmetic Act (21 U.S.C. 360j(m)) in ensuring the devel-
 14 opment of devices designed to treat or diagnose diseases
 15 or conditions that affect fewer than 4,000 pediatric pa-
 16 tients in the United States. Such report shall include the
 17 number and importance of devices for pediatric patients
 18 that are receiving exemptions under section 520(m) of the
 19 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 20 360j(m)).

21 **SECTION 1. SHORT TITLE.**

22 *This Act may be cited as the “Medical Devices Tech-*
 23 *nical Corrections Act”.*

1 **SEC. 2. TECHNICAL CORRECTIONS REGARDING PUBLIC LAW**

2 **107-250.**

3 (a) *TITLE I; FEES RELATING TO MEDICAL DE-*
 4 *VICES.—Part 3 of subchapter C of chapter VII of the Fed-*
 5 *eral Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.),*
 6 *as added by section 102 of Public Law 107-250 (116 Stat.*
 7 *1589), is amended—*

8 (1) *in section 737—*

9 (A) *in paragraph (4)(B), by striking “and*
 10 *for which clinical data are generally necessary to*
 11 *provide a reasonable assurance of safety and ef-*
 12 *fectiveness” and inserting “and for which sub-*
 13 *stantial clinical data are necessary to provide a*
 14 *reasonable assurance of safety and effectiveness”;*

15 (B) *in paragraph (4)(D), by striking “man-*
 16 *ufacturing,”;*

17 (C) *in paragraph (5)(J), by striking “a*
 18 *premarket application” and all that follows and*
 19 *inserting “a premarket application or premarket*
 20 *report under section 515 or a premarket applica-*
 21 *tion under section 351 of the Public Health Serv-*
 22 *ice Act.”; and*

23 (D) *in paragraph (8), by striking “The*
 24 *term ‘affiliate’ means a business entity that has*
 25 *a relationship with a second business entity”*
 26 *and inserting “The term ‘affiliate’ means a busi-*

ness entity that has a relationship with a second business entity (whether domestic or international)”; and

(2) in section 738—

(A) in subsection (a)(1)—

(i) in subparagraph (A)—

(I) in the matter preceding clause

(i) by striking “subsection (d),” and inserting “subsections (d) and (e),”;

(II) in clause (iv), by striking “clause (i),” and all that follows and inserting “clause (i).”; and

(III) in clause (vii), by striking “clause (i),” and all that follows and inserting “clause (i), subject to any adjustment under subsection (e)(2)(C)(ii).”; and

(ii) in subparagraph (D), in each of clauses (i) and (ii), by striking “application” and inserting “application, report,”;

(B) in subsection (d)(2)(B), beginning in the second sentence, by striking “firms. which show” and inserting “firms, which show”;

(C) in subsection (e)—

(i) in paragraph (1), by striking “Where” and inserting “For fiscal year 2004 and each subsequent fiscal year, where”; and

(ii) in paragraph (2)—

(I) in subparagraph (B), beginning in the second sentence, by striking “firms. which show” and inserting “firms, which show”; and

(II) in subparagraph (C)(i), by striking “Where” and inserting “For fiscal year 2004 and each subsequent fiscal year, where”;

(D) in subsection (f), by striking “for filing”; and

(E) in subsection (h)(2)(B)—

(i) in clause (ii), by redesignating subclauses (I) and (II) as items (aa) and (bb), respectively;

(ii) by redesignating clauses (i) and (ii) as subclauses (I) and (II), respectively;

(iii) by striking “The Secretary” and inserting the following:

“(i) IN GENERAL.—The Secretary”;
and

1 (iv) by adding at the end the following:

2 “(ii) *MORE THAN 5 PERCENT.*—To the
3 *extent such costs are more than 5 percent*
4 *below the specified level in subparagraph*
5 *(A)(ii), fees may not be collected under this*
6 *section for that fiscal year.”.*

7 (b) *TITLE II; AMENDMENTS REGARDING REGULATION*
8 *OF MEDICAL DEVICES.*—

9 (1) *INSPECTIONS BY ACCREDITED PERSONS.*—
10 *Section 704(g) of the Federal Food, Drug, and Cos-*
11 *metic Act (21 U.S.C. 374(g)), as added by section 201*
12 *of Public Law 107–250 (116 Stat. 1602), is amend-*
13 *ed—*

14 (A) in paragraph (1), in the first sentence,
15 by striking “conducting inspections” and all that
16 follows and inserting “conducting inspections of
17 establishments that manufacture, prepare, propa-
18 gate, compound, or process class II or class III
19 devices, which inspections are required under
20 section 510(h) or are inspections of such estab-
21 lishments required to register under section
22 510(i).”;

23 (B) in paragraph (6)(A)—

24 (i) in clause (i), by striking “of the es-
25 tablishment pursuant to subsection (h) or

1 *(i) of section 510” and inserting “described*
 2 *in paragraph (1)”;*

3 *(ii) in clause (ii)—*

4 *(I) in the matter preceding sub-*
 5 *clause (I)—*

6 *(aa) by striking “each in-*
 7 *spection” and inserting “inspec-*
 8 *tions”; and*

9 *(bb) by inserting “during a*
 10 *2-year period” after “person”;*
 11 *and*

12 *(II) in subclause (I), by striking*
 13 *“such a person” and inserting “an ac-*
 14 *credited person”;*

15 *(iii) in clause (iii)—*

16 *(I) in the matter preceding sub-*
 17 *clause (I), by striking “and the fol-*
 18 *lowing additional conditions are met:”*
 19 *and inserting “and 1 or both of the fol-*
 20 *lowing additional conditions are met.”;*

21 *(II) in subclause (I), by striking*
 22 *“under subclause (II) of this clause”*
 23 *and inserting “under clause (ii)(II)”;*
 24 *and*

1 (III) in subclause (II), by insert-
 2 ing “or by a person accredited under
 3 paragraph (2)” after “by the Sec-
 4 retary”;

5 (iv) in clause (iv)(I)—

6 (I) in the first sentence—

7 (aa) by striking “the two im-
 8 mediately preceding inspections of
 9 the establishment” and inserting
 10 “inspections of the establishment
 11 during the previous 4 years”; and

12 (bb) by inserting “section”
 13 after “pursuant to”;

14 (II) in the third sentence—

15 (aa) by striking “the petition
 16 states a commercial reason for the
 17 waiver;”; and

18 (bb) by inserting “not” after
 19 “the Secretary has not determined
 20 that the public health would”; and

21 (III) in the fourth sentence, by
 22 striking “granted until” and inserting
 23 “granted or deemed to be granted
 24 until”; and

25 (v) in clause (iv)(II)—

1 (I) by inserting “of a device estab-
 2 lishment required to register” after “to
 3 be conducted”; and

4 (II) by inserting “section” after
 5 “pursuant to”;

6 (C) in paragraph (6)(B)(iii)—

7 (i) in the first sentence, by striking “,
 8 and data otherwise describing whether the
 9 establishment has consistently been in com-
 10 pliance with sections 501 and 502”; and

11 (ii) in the second sentence—

12 (I) by striking “inspections” and
 13 inserting “inspectional findings”; and

14 (II) by inserting “relevant” after
 15 “together with all other”;

16 (D) in paragraph (6)(C)(ii), by striking “in
 17 accordance with section 510(h), or has not dur-
 18 ing such period been inspected pursuant to sec-
 19 tion 510(i), as applicable”;

20 (E) in paragraph (10)(B)(iii), by striking
 21 “a reporting” and inserting “a report”; and

22 (F) in paragraph (12)—

23 (i) by striking subparagraph (A) and
 24 inserting the following:

1 “(A) the number of inspections conducted by
 2 accredited persons pursuant to this subsection
 3 and the number of inspections conducted by Fed-
 4 eral employees pursuant to section 510(h) and of
 5 device establishments required to register under
 6 section 510(i);” and

7 (ii) in subparagraph (E), by striking
 8 “obtained by the Secretary” and all that
 9 follows and inserting “obtained by the Sec-
 10 retary pursuant to inspections conducted by
 11 Federal employees;”.

12 (2) OTHER CORRECTIONS.—

13 (A) PROHIBITED ACTS.—Section 301(gg) of
 14 the Federal Food, Drug, and Cosmetic Act (21
 15 U.S.C. 331(gg)), as amended by section 201(d) of
 16 Public Law 107–250 (116 Stat. 1609), is amend-
 17 ed to read as follows:

18 “(gg) The knowing failure to comply with paragraph
 19 (7)(E) of section 704(g); the knowing inclusion by a person
 20 accredited under paragraph (2) of such section of false in-
 21 formation in an inspection report under paragraph (7)(A)
 22 of such section; or the knowing failure of such a person to
 23 include material facts in such a report.”.

24 (B) ELECTRONIC LABELING.—Section
 25 502(f) of the Federal Food, Drug, and Cosmetic

1 *Act (21 U.S.C. 352(f)), as amended by section*
 2 *206 of Public Law 107–250 (116 Stat. 1613), is*
 3 *amended, in the last sentence—*

4 (i) *by inserting “or by a health care*
 5 *professional and required labeling for in*
 6 *vitro diagnostic devices intended for use by*
 7 *health care professionals or in blood estab-*
 8 *lishments” after “in health care facilities”;*

9 (ii) *by inserting a comma after*
 10 *“means”;*

11 (iii) *by striking “requirements of law*
 12 *and, that” and inserting “requirements of*
 13 *law, and that”;*

14 (iv) *by striking “the manufacturer af-*
 15 *fords health care facilities the opportunity”*
 16 *and inserting “the manufacturer affords*
 17 *such users the opportunity”; and*

18 (v) *by striking “the health care facil-*
 19 *ity”.*

20 (c) *TITLE III; ADDITIONAL AMENDMENTS.—*

21 (1) *EFFECTIVE DATE.—Section 301(b) of Public*
 22 *Law 107–250 (116 Stat. 1616), is amended by strik-*
 23 *ing “18 months” and inserting “36 months”.*

24 (2) *PREMARKET NOTIFICATION.—Section 510(o)*
 25 *of the Federal Food, Drug, and Cosmetic Act (21*

1 *U.S.C. 360(o)), as added by section 302(b) of Public*
 2 *Law 107–250 (116 Stat. 1616), is amended—*

3 *(A) in paragraph (1)(B), by striking “,*
 4 *adulterated” and inserting “or adulterated”; and*
 5 *(B) in paragraph (2)—*

6 *(i) in subparagraph (B), by striking “,*
 7 *adulterated” and inserting “or adulter-*
 8 *ated”; and*

9 *(ii) in subparagraph (E), by striking*
 10 *“semicritical” and inserting “semi-critical”.*

11 *(d) MISCELLANEOUS CORRECTIONS.—*

12 *(1) CERTAIN AMENDMENTS TO SECTION 515.—*

13 *(A) IN GENERAL.—*

14 *(i) TECHNICAL CORRECTION.—Section*
 15 *515(c) of the Federal Food, Drug, and Cos-*
 16 *metic Act (21 U.S.C. 360e(c)), as amended*
 17 *by sections 209 and 302(c)(2)(A) of Public*
 18 *Law 107–250 (116 Stat. 1613, 1618), is*
 19 *amended by redesignating paragraph (3)*
 20 *(as added by section 209 of such Public*
 21 *Law) as paragraph (4).*

22 *(ii) MODULAR REVIEW.—Section*
 23 *515(c)(4)(B) of the Federal Food, Drug, and*
 24 *Cosmetic Act (21 U.S.C. 360e(c)(4)(B)) is*
 25 *amended by striking “unless an issue of*

1 *safety” and inserting “unless a significant*
 2 *issue of safety”.*

3 (B) *CONFORMING AMENDMENT.*—Section
 4 210 of Public Law 107–250 (116 Stat. 1614) is
 5 amended by striking “, as amended” and all that
 6 follows through “by adding” and inserting “is
 7 amended in paragraph (3), as redesignated by
 8 section 302(c)(2)(A) of this Act, by adding”.

9 (2) *CERTAIN AMENDMENTS TO SECTION 738.*—

10 (A) *IN GENERAL.*—Section 738(a) of the
 11 Federal Food, Drug, and Cosmetic Act (21
 12 U.S.C. 379j(a)), as amended by subsection (a), is
 13 amended—

14 (i) *in the matter preceding paragraph*

15 (1)—

16 (I) *by striking “(a) TYPES OF*
 17 *FEES.—Beginning on” and inserting*
 18 *the following:*

19 “(a) *TYPES OF FEES.*—

20 “(1) *IN GENERAL.—Beginning on”; and*

21 (II) *by striking “this section as*
 22 *follows:” and inserting “this section.”;*
 23 *and*

(ii) by striking “(1) *PREMARKET APPLICATION*,” and inserting the following:
“(2) *PREMARKET APPLICATION*,”.

(B) *CONFORMING AMENDMENTS*.—Section 738 of the *Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 379j), as amended by subparagraph (A), is amended—

(i) in subsection (d)(1), in the last sentence, by striking “subsection (a)(1)(A)” and inserting “subsection (a)(2)(A)”;

(ii) in subsection (e)(1), by striking “subsection (a)(1)(A)(vii)” and inserting “subsection (a)(2)(A)(vii)”;

(iii) in subsection (e)(2)(C)—

(I) in each of clauses (i) and (ii), by striking “subsection (a)(1)(A)(vii)” and inserting “subsection (a)(2)(A)(vii)”;

(II) in clause (ii), by striking “subsection (a)(1)(A)(i)” and inserting “subsection (a)(2)(A)(i)”;

(iv) in subsection (j), by striking “subsection (a)(1)(D),” and inserting “subsection (a)(2)(D),”.

1 (C) *ADDITIONAL CONFORMING AMEND-*
 2 *MENT.—Section 102(b)(1) of Public Law 107–*
 3 *250 (116 Stat. 1600) is amended, in the matter*
 4 *preceding subparagraph (A), by striking “section*
 5 *738(a)(1)(A)(ii)” and inserting “section*
 6 *738(a)(2)(A)(ii)”.*

7 (3) *PUBLIC LAW 107–250.—Public Law 107–250*
 8 *is amended—*

9 (A) *in section 102(a) (116 Stat. 1589), by*
 10 *striking “(21 U.S.C. 379F et seq.)” and inserting*
 11 *“(21 U.S.C. 379f et seq.)”;*

12 (B) *in section 102(b) (116 Stat. 1600)—*

13 (i) *by striking paragraph (2);*

14 (ii) *in paragraph (1), by redesignating*
 15 *subparagraphs (A) and (B) as paragraphs*
 16 *(1) and (2), respectively; and*

17 (iii) *by striking:*

18 “(b) *FEE EXEMPTION FOR CERTAIN ENTITIES SUB-*
 19 *MITTING PREMARKET REPORTS.—*

20 “(1) *IN GENERAL.—A person submitting a pre-*
 21 *market report” and inserting:*

22 “(b) *FEE EXEMPTION FOR CERTAIN ENTITIES SUB-*
 23 *MITTING PREMARKET REPORTS.—A person submitting a*
 24 *premarket report”; and*

1 (C) in section 212(b)(2) (116 Stat. 1614),
2 by striking “, such as phase IV trials,”.

3 **SEC. 3. REPORT ON BARRIERS TO AVAILABILITY OF DE-**
4 **VICES INTENDED FOR CHILDREN.**

5 Not later than 180 days after the date of enactment
6 of this Act, the Secretary of Health and Human Services
7 shall submit to the Committee on Health, Education, Labor,
8 and Pensions of the Senate and the Committee on Energy
9 and Commerce of the House of Representatives a report on
10 the barriers to the availability of devices intended for the
11 treatment or diagnosis of diseases and conditions that affect
12 children. The report shall include any recommendations of
13 the Secretary of Health and Human Services for changes
14 to existing statutory authority, regulations, or agency pol-
15 icy or practice to encourage the invention and development
16 of such devices.

Calendar No. 412

108TH CONGRESS
1ST SESSION

S. 1881

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to make technical corrections relating to the amendments made by the Medical Device User Fee and Modernization Act of 2002, and for other purposes.

NOVEMBER 24, 2003

Reported with an amendment